NOV 28 2011

Raptor™ Facet Fixation System

510(k) SUMMARY
July 2011

Submitter: Alphatec Spine, Inc.
5818 El Camino Real
Carlsbad, CA 92008
Direct: (760) 494-6739
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Official Contact: Olga Lewis, Regulatory Affairs Specialist

Trade/Model Name: Raptor™ Facet Fixation System

Common or Usual Name: Posterior Facet Screw and Washer

Classification Regulation: MRW - system, facet screw spinal device

Device Description:

The Raptor™ Facet Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The system is comprised of the Facet Screw with Washer and instrumentation. The implant provides bilateral facet fixation, with or without bone graft, at single or multiple levels and can be used in conventional or percutaneous surgical procedures. The implants are manufactured from surgical grade titanium alloy (Ti-6Al-4V ELI).

Indications for Use

The Raptor™ Facet Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. Raptor™ Facet Fixation System is intended for bilateral facet fixation, with or without bone graft, at single or multiple levels form L1-S1 inclusive. The Raptor™ Facet Fixation System is indicated for treatment of any or all of the following:

- degenerative disc disease (DDD) as defined by back pain of discogenic origins confirmed by history and radiographic studies
- degenerative disease of the facets with instability
- trauma (i.e. fracture or dislocation)
- spondylolisthesis
- spondylolysis
- pseudoarthrosis and failed previous fusion which are symptomatic or which may cause secondary instability or deformity

Raptor™ Facet Fixation System

Predicate Devices:

Capture™ Facet Fixation System K092464
Interventional Spine, Inc .PERPOS FCD-2 System K090767
Osteomed Spine Inc. PrimaLOK Facet Fixation System K102438
X-Spine Systems Inc. Fixcet Spinal Fixation Screw System K100154
SpineFrontier Chameleon Fixation System k071420

Technological Characteristics Comparison:

The Raptor™ Facet Fixation System is substantially equivalent to the referenced devices in that it is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. It is similar in terms of general design, intended use, and technological characteristics to the predicate device.

Material composition is identical to numerous other Alphatec Spine products that have been cleared via the 510(k) process.

Nonclinical Performance Data:

Mechanical testing was performed that provides reasonable assurance of safety and effectiveness for its intended use. Performance testing was performed per the recognized consensus standards and per the guidance document, *Spinal System 510(k)s - Guidance for Industry and FDA Staff.*

The following testing was performed for the determination of substantial equivalence:

- Insertion/Removal Torque according to ASTM F543-07
- Torque to failure – The torsional yield strength and breaking angle according to ASTM F543-07
- Axial Pullout Strength according to ASTM F543-07
- Static Bending according to ASTM-F2193-02(2007)
- Dynamic Bending according to ASTM-F2193-02(2007)

This testing demonstrated that the performance characteristics satisfy the requirements of posterior supplemental fixation. As a result of this testing and an engineering analysis, the Raptor™ Facet Fixation System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Alphatec Spine, Inc.
% Ms. Olga Lewis
Regulatory Affairs Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K110170
Trade/Device Name: Raptor™ Facet Fixation System
Regulatory Class: Unclassified
Product Code: MRW
Dated: November 10, 2011
Received: November 14, 2011

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

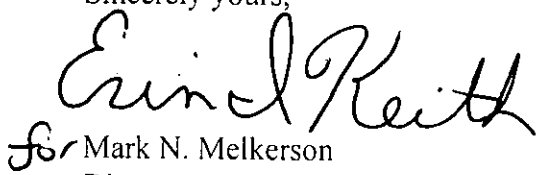
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Raptor™ Facet Fixation System

Section 11 Indications for Use Statement

510(k) Number (if known): k110170

Device Name: Raptor™ Facet Fixation System

Indications for Use:

The Raptor™ Facet Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. Raptor™ Facet Fixation System is intended for bilateral facet fixation, with or without bone graft, at single or multiple levels from L1-S1 inclusive. The Raptor™ Facet Fixation System is indicated for treatment of any or all of the following:

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Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110170